IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Toby Freyman, Timothy J. Mickley, Maria J. Palasis, Wendy Naimark**
Application No.:	**10/645653**
Filed:	**August 20, 2003**
For:	**Medical Device with Drug Delivery Member**
Examiner:	**Catherine Witczak**
Group Art Unit:	**3767**

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Commissioner for Patents
P.O. Box 1450
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Docket No.: S63.2B-14157-US01

REPLY BRIEF

This is a Reply Brief being filed in response to the Examiner's Answer mailed February 19, 2009. Claims 25-40 have been twice or finally rejected and are the subject of the appeal.

A Notice of Appeal was filed in this case on September 29, 2008. The fees required under § 1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account 22-03 50 for any other fees which may be due with this appeal.

Reply to Examiner's Answer

Rejection under 35 U.S.C. §103(a)

The rejection of claims 25-40 under 35 U.S.C. §103(a) as being obvious over Clark et al (US 5,713,853) as modified by Ding et al (US 6,364,856) has been maintained.

Independent claim 25 is directed to an embodiment of a medical device having, inter alia, a self-expanding delivery member "shaped in a continuous solid cylindrical configuration".

I. No Prima Facie Obviousness

No *prima facie* showing of obviousness has been established with respect to claim 25 using the combination of Clark et al. and Ding et al. The combination fails to disclose or suggest a self-expanding delivery member shaped in a continuous solid configuration as will be shown below. *Prima facie* obviousness under 35 U.S.C. §103 requires that the combination of references teach or suggest all of the claim limitations, The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

As asserted the Final Office Action dated 5/28/2008, Clark et al. disclose

> … a medical device comprising a shaft (702); an initially cylindrically shaped delivery member (706); a therapeutic agent delivery lumen (710) connected to a therapeutic agent source; a retention member (704); and a therapeutic agent source being a syringe which is capable of applying negative pressure.
>
> Final Office Action, p. 2, no. 1

It is not disputed that Clark et al. fail to disclose or suggest a " ... delivery member being shaped in a continuously solid cylindrical configuration." Final Office Action, p. 2, no. 1. The Examiner further asserted, however, that Ding et al. teach in Figures 2 and 3 that it is known to use a delivery member having a continuous solid cylindrical shape. It would have been obvious to modify the device of Clark with a continuously solid delivery member (asserted by the Examiner to be disclosed by Ding) since such a structure would ensure maximum contact with the treatment area when the delivery member is in its expanded state." Final Office Action, p. 2, no. 1.

Applicants dispute that Ding et al. disclose a balloon being in a solid cylindrical configuration, and submit that the combination therefore fails to disclose or suggest a self-expanding delivery member in a shaped in a continuous solid cylindrical configuration as recited in claim 25.

In response the Examiner now asserts the following:

> In response to Appellant's argument that Ding et at do not disclose a balloon being shaped in a solid cylindrical configuration, Examiner points to Figures 1b, 3 and 4b in which Ding et al disclose a balloon having, in its center section, a solid cylindrical configuration. Although the ends of the balloons in Ding et al's figures may be tapered, Examiner points out that there is no limitation in the claim that requires the entire length of the balloon to be a solid cylindrical configuration, and that furthermore Appellant themselves disclose in their figures that only middle portion (18) is cylindrical while distal and proximal ends (54 and 50) are tapered. Clearly Ding et al teaches the use of a porous material as noted by appellant on pages 11 and 12 of the appeal brief.
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> Examiner's Answer, p. 4, Response to Arguments

Applicants disagree and submit that the embodiments of Figures 1b, 3 and 4b, are not directed to a balloon having a solid cylindrical configuration.

Ding et al. disclose with respect to Figure 1b, the following:

> The catheter 1 comprises an expandable portion 2 having a balloon 3 disposed about the catheter 1. The outer surface of the balloon 3 is covered with a sponge coating 4 of a non-hydrogel polymer having a plurality of voids 10 therein. A drug 5 is placed into the voids 10. An inflation lumen 6 is connected to the balloon 3 to fill the balloon 3 with fluid, such as a liquid, or pressurized gas, and to expand the balloon 3. A protective sheath 7 can be placed around the expandable portion 2 to prevent the drug 5 from being inadvertently released during insertion of the catheter 1 into the body lumen 8.
>
> Column 3, lines 37-47

There is nothing in the disclosure of Ding et al. with respect to Figure 1b that would suggest to one of ordinary skill in the art that this balloon is anything other than a conventional balloon, formed having a lumen therethrough, wherein the balloon is filled with inflation fluid to expand it from its unexpanded state to its expanded state. There is certainly nothing to suggest it is a shaped solid cylindrical member as recited in claim 25. In fact, having the sponge coating with voids for placing drugs therein, would suggest the opposite.

Ding et al. disclose with respect to the embodiment of Figure 3, the following:

> FIG. 3 illustrates yet another embodiment of a catheter 1 in its expanded state wherein the balloon 3 and reservoir 12 of the embodiment of FIGS. 2a and 2b are combined. In this embodiment, drug 5 is placed into the balloon 3 through the inflation lumen 6 to expand the balloon 3. In other words by filling the balloon 3 with a fluid or composition containing the drug 5, the balloon 3 is expanded. The force of expansion causes the drug 5 in the balloon 3 to infuse the drug 5 into the voids 10 of the sponge coating 4. By expanding the balloon 3 further the drug 5 can be released from the sponge coating 4 into afflicted tissue 9.
>
> Column 4, lines 27-38

Again, there is nothing in this disclosure that would suggest that this balloon is anything other than a conventional expandable medical balloon wherein the lumen of the balloon is filled with fluid to expand the balloon from a deflated state.

Again, the presence of the sponge coating is in opposition to a balloon that is a solid cylindrical configuration as recited in claim 25.

Likewise for Figure 4 wherein Ding et al. again disclose the following:

> FIGS. 4a and 4b shows the delivery and deployment of a balloon expandable stent 15 by a catheter 1 coated with a sponge coating 4 having a drug 5 infused into the voids 10 of the sponge coating 4. The stent 15 is disposed on the expandable portion 2 of the catheter 1 for delivery as in FIG. 4a. The stent can also be coated with a sponge coating, particularly one where the particulate material is a drug. The stent 15 is implanted by expanding the balloon 3 to force open the stent. Also, as shown in FIG. 4b, when the stent 15 is deployed, expansion of the balloon 3 causes the drug 5 to infuse into the voids 10 of the sponge coating 4 and to be released into the body lumen 8.
>
> Col. 4, lines 60-67 and col. 5, lines 1-4

The combination simply fails to disclose or suggest a self-expanding delivery member shaped in a continuous solid cylindrical configuration as recited in claim 1. At most, the combination may suggest to one of ordinary skill in the art to employ the sponge coating of Ding et al. on the Clark balloon, but not a solid delivery member of the type recited in claim 25.

No *prima facie* showing of obviousness has been established with respect to claim 25 using the combination of Clark et al. and Ding et al. *Prima facie* obviousness under 35 U.S.C. §103 requires that the combination of references teach or suggest all of the claim limitations, The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

It is further argued in the Examiner's Answer, that:

> In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F 2d 1071, 5 USPQ2d 1596 (Fed.. Cit.. 1988) and *In re Jones*, 958 F .2d 347, 21 USPQ2d 1941 (Fed Cir.. 1992) In this case, it would have been obvious to combine the references of Clark and Ding, because it is the shaft structure in combination with a therapeutic agent delivery lumen, initially cylindrically shaped delivery member, therapeutic agent source, retention member, and syringe of Clark that one of ordinary skill in the art would be looking to combine with Ding's device NOT the delivery member itself of Clark's device.
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> Examiner's Answer, pp. 4-5, Response to Argument

However, as discussed above, the Ding et al. balloon is not shaped in a solid continuous cylindrical configuration. Therefore, the combination does not produce the requisite features of claim 25 whether there is a reason to combine these references or not. At most, the combination leads to the use of a sponge coating as disclosed by Ding et al., on the device of Clark et al.

The following is also asserted in the Examiner's Answer:

> It is the Examiner's position that besides disclosing a system comprising a delivery member with spaced ribs which are intended to allow the device to serve as a thrombolytic filter or which allow the device to deliver drugs to a vessel without blocking blood flow, Clark discloses a second system, as described in column 3, lines 56-60: "a method of delivering drugs or other agents to a lumen comprising advancing a catheter having compressed delivery members, releasing the delivery members, and delivering drugs or other agents through the catheter and delivery members." It is this second system (not the first as argued by the Appellant) that the Examiner is relying on for the basis of the obviousness rejection. The second system makes no reference of the delivery member functioning to serve as a filter or to allow blood to flow through when expanded; instead this second system of Clark is simply drawn to a method of positioning a drug releasing expandable member within a lumen.. It is the Examiner's position that it would be obvious to modify this system with a delivery member as taught by Ding. Although Ding

> does not explicitly state why a solid cylindrical shape is used from the device, Ding discloses in column 4, lines 3-6 that "additional expansion of the balloon causes the drug, which is in the sponge coating to be released from the sponge coating into the afflicted tissue".
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> Examiner's Answer, pp. 5-6, Response to Arguments

Again, Applicants disagree.

Even if the second system is for the purpose of delivering drugs, without mention that it functions as a filter, the device at col. 3, lines 56-60, must still be construed in accordance with the Clark et al. disclosure, i.e., it comprises a plurality of delivery members wherein blow flow is not impeded by the delivery members. See column 3, lines 56-60. That the device of Clark et al. not impede blood flow is a theme carried throughout the Clark et al. disclosure. Thus, the lack of such device functioning as a filter is inconsequential because one of the Clark et al. objectives is a device wherein blow flow is not impeded, regardless of the presence of a filtering effect. In fact, filtering is not discussed for any of the embodiments up to Figure 17 (see col. 12, lines 61-62). However, in each embodiment, there is a plurality of members that flare toward the wall of a vessel and do not impede the flow of fluids. Col. 3, lines 52-55. For example, refer to Figure 5 and col. 9, lines 62-63 wherein filtering is not discussed, but the "[p]erfusion of blood is not impeded, as blood or other fluids will flow between the delivery members." Col. 9, lines 62-63.

The Examiner goes on to assert that:

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> As would be obvious to one having ordinary skill in the art at the time the invention was made, the larger the surface area of the balloon, the greater the contact surface with the tissue and thus more drug is released to the tissue,. For these reasons, it is the Examiner's position that it would be obvious to modify Clark's method of positioning a delivery device within a lumen with a solid cylindrical balloon as taught by Ding since such a

> modification would provide for an easily positionable member which efficiently disperses drugs to the surrounding lumen.
> Examiner's Answer, p. 6, Response to Arguments

However, Applicants submit that making reference to the surface area of these devices is off point. The point is, Applicants' device is a shaped continuous solid configuration. The devices of both Clark et al. and Ding et al., are hollow, i.e., they have lumens extending through the delivery member. See Clark et al., Summary of the Invention. Each delivery member has a lumen extending therethrough. Even if the Ding et al. device were solid, which it's not, one of skill in the art would simply not substitute a solid member for the Clark et al. delivery members because of Clark et al.'s teaching that blow flow not be impeded by the delivery members, regardless of what the surface area of the delivery member may be.

II. Even if Prima Facie Obviousness Could be Established, Teaching Away is Enough to Rebut a Showing of Prima Facie Obviousness

As previously discussed, even if the Ding et al. device were in a shaped solid cylindrical configuration, which it is not, Clark et al. actually teach away from employing a solid member. Clark et al.'s goal is to deliver drugs proximate the walls of the vessel without blocking blood flow. See column 2, lines 48-51.

To that end, Clark et al. disclose, rather than a single delivery member, a plurality of delivery members 502 with spaced ribs 702. The members or ribs of Clark are intended to allow the device to serve as a thrombolytic filter. The ribs can be solid or can define a series or ports or lumens (column 12, lines 6 1-65), but in any case they are configured to allow blood to flow to tissue distal to the delivery site through the regions defined by the ribs (column 14, lines 38-40). If the device is modified to contain a

delivery member with a continuous solid cylindrical configuration without gaps between ribs, it would no longer allow for blood to reach tissue distal the delivery site and would no longer perform act as a filter.

As discussed above, in the Background of the Invention, Clark et al. state:

> It is known that the velocity of fluid flow through a tube varies across the axial cross-section of the tube. The velocity is maximum at the center of the tube and approaches zero at the walls. In an artery or a vein, blood flow is very slow in the region proximate the walls. If drugs or other agents could be effectively delivered proximate the walls, the blood or other fluid flow can atraumatically carry the delivered drug or agent over the site of interest. The delivered drug or agent would also not dissipate as rapidly as drug delivered at the center of the vessel. Less drug could then need to be delivered, shortening procedures and decreasing their cost.
>
> A drug delivery device which could deliver drugs proximate the walls of the vessel without blocking blood flow, would be advantageous.
>
> Background of the Invention, col. 2, lines 35-51

Thus, based on the above, while Clark et al. certainly teach away from any modification that would require the delivery member to be configured in the manner recited in the instant claims, it is also apparent that a modification forcing Clark et al. to incorporate a delivery member having a continuous solid cylindrical configuration would interfere with the stated function of the Clark et al. device. Simply put, one of ordinary skill in the art would not seek to structurally modify the filter of Clark in such a way that it is no longer capable of acting as a filter.

Any solid cylindrical member would have an effect of impeding blood flow, in opposition to the Clark et al. device.

Secondary considerations, such as a teaching away from, are sufficient to overcome a *prima facie* showing of obviousness. Id. at 1390.

See also MPEP 2145 wherein it is stated that "[i]t is improper to combine

references where the references teach away from their combination." MPEP, 8th Ed. Rev. 6 (Sep. 2007) §2145(X)(D)(2); see also *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. 1740 (2007); *Takeda Chem. Indus., Ltd. v. Alphaphann Pty. Ltd.,* 492 F.3d 1350, 1358-59 (Fed. Cir. 2007) (finding the prior art taught away from the claims and the claims therefore were not invalid). Clark clearly shows and describes multiple delivery members or ribs (see elements 502 and 706 for examples) which collectively act as a filter to allow blood to flow therethrough while catching or removing a thrombus or plaque (column 12, lines 6 1-65 & column 14, lines 39-43). The filter described in Clark is clearly distinct from the continuous solid cylindrical member of the present application in both structure and function; regardless of the teaching of Ding, one of ordinary skill would have no reason to modify such a filter in a manner that would render the filter incapable of functioning as such.

To that end, in must also be noted that MPEP § 2143.01 states "If [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." In the present case there is no doubt that the Examiner's proposed modification of Clark would render the described filter unsatisfactory for its intended purpose.

CONCLUSION

Claims 25-40 are pending in the application and are the subject of this appeal. Claim 25 has not been rendered obvious by Clark et al. in view of Ding et al. Claims 26-40 which depend therefrom are also not obvious for at least these reasons.

Reversal of the rejection of claims 25-40 under 35 U.S.C. §103(a) as being obvious over Clark et al (US 5,713,853) as modified by Ding et al (US 6,364,856) has been maintained.

The attorney of record may be reached at (952)563-3011.

Respectfully submitted,

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